EXHIBIT 1

PSC's Responses to the SSC Defendants' 1st RFAs

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION MDI	L No. 2419
Dkt. THIS DOCUMENT RELATES TO: Suits Naming Specialty Surgery Center, Crossville, PLLC Dkt.	No. 1:13-md-2419 (RWZ)
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PLAINTIFFS' STEERING COMMITTEE'S RESPONSES TO SPECIALTY SURGERY CENTER, CROSSVILLE, PLLC, KENNETH R. LISTER, MD, AND KENNETH LISTER, MD, PC'S FIRST REQUESTS FOR ADMISSIONS PROPOUNDED TO THE PLAINTIFFS

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure, the Plaintiffs' Counsel hereby responds to the First Interrogatories and Requests for Admission Propounded by the Defendants, Specialty Surgery Center, Crossville, PLLC, Kenneth R. Lister, MD, and Kenneth Lister, MD, PC, (collectively "Defendants" or "SSC Defendants").

INSTRUCTIONS DEFINITIONS AND OBJECTIONS

- 1. The term "Plaintiffs" shall mean all Plaintiffs who have pending cases against any of the SSC Defendants in active cases in the MDL.
- 2. The term "Plaintiffs' Counsel" shall mean the Tennessee State Chair as designated by Plaintiffs' Steering Committee pursuant to MDL Order No. 2.

does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. See e.g., *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 111:

Exhibit E is an April 10, 2013, report from the Department of Health Human Services,

Office of Inspector General titled "High-Risk Compounded Sterile Preparations and Outsourcing
by Hospitals That Use Them, OEI-01-13-00150" addressed to Margaret Hamburg, MD,

Commissioner of the FDA.

RESPONSE TO REQUEST FOR ADMISSION NO. 111:

Admitted that Exhibit E is dated April 10, 2013 and appears to be a report from the Department of Health Human Services, Office of Inspector General titled "High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them, OEI-01-13-00150" addressed to Margaret Hamburg, MD, Commissioner of the FDA.

REQUEST FOR ADMISSION NO. 112:

Exhibit E is a record or statement of a public office as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 112:

Denied. The attached document lacks the trustworthiness required of Rule 803(8) to be admitted under Rule 803(8) and is not a record or statement as used in Rule 803(8) nor is it reference matters that were observed while "under a legal duty to report".

REQUEST FOR ADMISSION NO. 113:

The report attached as Exhibit E is reliable.

RESPONSE TO REQUEST FOR ADMISSION NO. 113:

Denied.

REQUEST FOR ADMISSION NO. 114:

Ninety-two percent (92%) of a representative sample of acute-care hospitals participating in Medicare used compounded sterile preparations in 2012.⁵⁸

RESPONSE TO REQUEST FOR ADMISSION NO. 114:

⁵⁸ Exhibit E.

information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 115:

Seventy-nine-point-four percent (79.4%) of a representative sample of acute-care hospitals participating in Medicare that used compounded sterile preparations outsourced the compounding to a supplier.⁵⁹

RESPONSE TO REQUEST FOR ADMISSION NO. 115:

⁵⁹ Exhibit E.

REQUEST FOR ADMISSION NO. 116:

Sixty-eight-point-one percent (68.1%) of a representative sample of acute-care hospitals participating in Medicare reported that shortages of commercial products were a very important factor when deciding whether to outsource compounded sterile preparations.⁶⁰

RESPONSE TO REQUEST FOR ADMISSION NO. 116:

⁶⁰ Exhibit E.

REQUEST FOR ADMISSION NO. 117:

Ninety-point-eight percent (90.8%) of a representative sample of acute-care hospitals participating in Medicare reported that shortages of commercial products was a very important or somewhat important factor when deciding whether to outsource compounded sterile preparations.⁶¹

RESPONSE TO REQUEST FOR ADMISSION NO. 117:

⁶¹ Exhibit E.

REQUEST FOR ADMISSION NO. 118:

Seventy-six-point-three percent (76.3%) of a representative sample of acute-care hospitals participating in Medicare reported that the need for special products was a very important or somewhat important factor when deciding whether to outsource compounded sterile preparations.⁶²

RESPONSE TO REQUEST FOR ADMISSION NO. 118:

⁶² Exhibit E.

REQUEST FOR ADMISSION NO. 119:

Eighty-five-point-nine percent (85.9%) of a representative sample of acute-care hospitals participating in Medicare reported that product cost was a very important or somewhat important factor when selecting a particular outside pharmacy to compound sterile preparations.⁶³

RESPONSE TO REQUEST FOR ADMISSION NO. 119:

⁶³ Exhibit E.

REQUEST FOR ADMISSION NO. 120:

Following the fungal meningitis outbreak, of the hospitals in the representative sample of acute-care hospitals participating in Medicare that outsourced the compounding of compounded sterile preparations, 83% required compliance with USP 797, 71% reviewed quality reports provided by the outside pharmacy, 27% reviewed quality reports provided by a third party, 22% conducted onsite visits at the outside pharmacy, and 9% tested the preparations provided by the outsource pharmacy.⁶⁴

RESPONSE TO REQUEST FOR ADMISSION NO. 120:

⁶⁴ Exhibit E.

information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 121:

Despite the survey taking place after the 2012 fungal meningitis outbreak, "few hospitals (11 of 236) in [the] sample reported problems with product contamination. . ."⁶⁵

RESPONSE TO REQUEST FOR ADMISSION NO. 121:

⁶⁵ Exhibit E.

Plaintiffs further object to this Request as it is vague in that the term "after the 2012 fungal meningitis outbreak" is ambiguous. Plaintiffs further object to this Request as the term "the survey" is vague.

REQUEST FOR ADMISSION NO. 122:

"Half of all hospitals made changes or planned to make changes to CSP sourcing practices in response to the fall 2012 outbreak[.] Overall, 56% of hospitals made changes to CSP sourcing practices in 2012 or plan to make changes in 2013."⁶⁶

RESPONSE TO REQUEST FOR ADMISSION NO. 122:

Plaintiffs object to this RFA as it is unlimited in time and Plaintiffs cannot admit or deny this RFA based on an unlimited timeframe. Plaintiffs further object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession

⁶⁶ Exhibit E.

of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises*, *Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 123:

The American Society of Health System Pharmacists ("ASHP") Research and Education Foundation's "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" was not released until June 29, 2011.

RESPONSE TO REQUEST FOR ADMISSION NO. 123:

Plaintiffs admit that there is a version of a document entitled, "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" that bears a copyright date of 2011. With regard to when this document was released, Plaintiffs state Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises*, *Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 131:

Exhibit F and Exhibit G identify health care providers and facilities that purchased products from NECC as determined by the FDA in carrying out its authorized activities.

RESPONSE TO REQUEST FOR ADMISSION NO. 131:

Admitted that Exhibits F and G are a list of customers that purchased products from NECC as compiled by either the FDA or NECC. As to the remaining allegations, Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs.*, *Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 132:

The health care providers and facilities identified in $\underline{\text{Exhibit }G}$ purchased the products from NECC in the amounts identified in $\underline{\text{Exhibit }G}$.

RESPONSE TO REQUEST FOR ADMISSION NO. 132:

Admitted that Exhibit G identifies customers that purchased products from NECC as compiled by either the FDA or NECC.

REQUEST FOR ADMISSION NO. 133:

Exhibit H identifies health care providers and facilities that purchased MPA from NECC and received product from lots #05212012@68, #06292012@26, and #08102012@51 compounded by NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 133:

Admitted that Exhibit H identifies customers that purchased products from NECC as compiled by the CDC.

REQUEST FOR ADMISSION NO. 134:

Exhibits F, G, and H are records and data compilations of public agencies as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 134:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 135:

The Plaintiffs' Steering Committee and/or individual Plaintiffs or counsel for individual Plaintiffs used or relied upon Exhibit F and/or Exhibit G to identify or allege that specific health care providers purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 135:

Plaintiffs object to this RFA to the extent that it seeks information not reasonably calculated to lead to the discovery of admissible evidence, is overly broad, unduly burdensome, and vague. Plaintiffs further object to the extent that this RFA seeks information that is covered by any applicable privilege.

REQUEST FOR ADMISSION NO. 136:

The Plaintiffs' Steering Committee and/or the individual Plaintiffs or counsel for the individual Plaintiffs used or relied upon Exhibit H to identify or allege that specific health care providers purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 136:

Plaintiffs object to this RFA to the extent that it seeks information not reasonably calculated to lead to the discovery of admissible evidence, is overly broad, unduly burdensome, and vague. Plaintiffs further object to the extent that this RFA seeks information that is covered by any applicable privilege.

REQUEST FOR ADMISSION NO. 137:

Between May 21, 2012, and October 6, 2012, more than 50 health care facilities/providers in Tennessee purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 137:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in Tennessee that purchased any medication from NECC. Subject to and without waiving this objection, after making a

reasonable investigation, Plaintiffs are without sufficient information to admit or deny this request.

REQUEST FOR ADMISSION NO. 138:

Between May 21, 2012, and October 6, 2012, more than 180 health care facilities/providers in the United States purchased MPA from NECC.⁷¹

RESPONSE TO REQUEST FOR ADMISSION NO. 138:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. See e.g., Henry v. Champlain Enterprises, Inc., 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

⁷¹ Attached as Exhibit I is a summary of the information from Exhibit G, showing only the health care providers/facilities that purchased methylprednisolone acetate from NECC.

REQUEST FOR ADMISSION NO. 139:

Between May 21, 2012, and October 6, 2012, more than 90 health care facilities/providers in the United States purchased *preservative-free* MPA from NECC.⁷²

RESPONSE TO REQUEST FOR ADMISSION NO. 139:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any preservative free MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. See e.g., Henry v. Champlain Enterprises, Inc., 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 140:

Between May 21, 2012, and October 6, 2012, more than 3,000 health care facilities/providers in the United States purchased medication from NECC.

⁷² Attached as Exhibit J is a summary of the information from Exhibit G, showing only the health care providers/facilities that purchased preservative-free methylprednisolone acetate from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 140:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. See e.g., Henry v. Champlain Enterprises, Inc., 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 141:

Brigham and Women's Hospital performed an on-site audit of NECC in May 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 141:

Admit that an agent of Brigham and Women's Hospital visited NECC in May of 2012. Denied as to all other allegations in this RFA.

REQUEST FOR ADMISSION NO. 142:

Brigham and Women's Hospital continued purchasing from NECC after performing the on-site audit, and purchased product until at least September 18, 2012.⁷³

RESPONSE TO REQUEST FOR ADMISSION NO. 142:

Admit that Exhibits F and G show that Brigham and Women's Hospital purchased products from NECC after May of 2012. Denied as to all other allegations in this RFA.

Dated: December 23, 2014 Respectfully submitted,

/s/ J. Gerard Stranch, IV

Nashville, TN 37201

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Plaintiffs' Counsel

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⁷³ See Exhibits F and G.